

121



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,210	08/27/2003	David B. Reitz		6144

7590 03/23/2004

PHARMACIA CORPORATION
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Corporate Patent Department
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Chesterfield, MO 63006

EXAMINER

STOCKTON, LAURA

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/649,210

Applicant(s)

REITZ ET AL.

Examiner

Laura L. Stockton, Ph.D.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-27 are pending in the application.

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78). The entire history of prior applications has not been provided. Note that the Declaration was executed in March of 1993.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C.

112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-15, 18, 19, 22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out

and distinctly claim the subject matter which applicant regards as the invention.

In claim 2, the R¹, R² and R³ variables representing a N,N-dimethylamino or a N,N-diethylamino lacks antecedent basis from claim 1. It states in claim 1 that R¹, R² and R³ can represent amino or alkylamino but does not state that R¹, R² and R³ can represent a dialkylamino.

Since none of the variables R¹, R² and R³ represent a hydrido in claims 18 and 22, the proviso at the end of claims 18 and 22 is confusing.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 7-12 and 14 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-7, respectively, of prior U.S.

Patent No. 6,630,497. This is a double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 13 and 15-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7, 8, 11-15, 17, 18, 21-25, 27, 28 and 31-33 of U.S. Patent No. 5,087,634 and over claims 1-10 of U.S. Patent No. 5,238,952. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

The indiscriminate selection of “some” among “many” is *prima facie* obvious. The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., treating circulatory disorders).

One skilled in the art would have been motivated to prepare compounds embraced by the each of the patents stated above to arrive at the instant claimed compounds with the expectation of obtaining additional beneficial N-substituted imidazol-2-one compounds which would be useful in treating circulatory disorders, glaucoma, etc. The

instant claimed N-substituted imidazol-2-one compounds would have been suggested to one skilled in the art and therefore, the instant claimed compounds would have been obvious to one skilled in the art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 13 and 15-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reitz et al. {U.S. Pat. 5,087,634}.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicants claim N-substituted imidazol-2-one compounds that are useful in treating circulatory disorders. Reitz et al. (columns 2-3) teach N-substituted imidazol-2-one compounds, which are structurally similar

to the instant claimed compounds, that are useful in treating circulatory disorders and glaucoma (column 5, lines 45-63).

See “a more preferred class of compounds” in column 8, lines 50-53; column 9, lines 1, 2, 15, 45 and 46; column 10, lines 66-68 and column 11, lines 1 and 2. Additionally see a “sub-class of compounds of high interest as represented by Formula III” in column 54, lines 53-68 and column 55, lines 1-16. Especially note the compound in column 55, lines 47-49 and the teaching in the reference that the phenyl on the 1-position of the imidazole-2-one (represented by the R¹ variable) can be substituted in a substitutable position with one or more substituents such as alkyl, halo and alkoxy (column 8, lines 14-25).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The indiscriminate selection of “some” among “many” is *prima facie* obvious. The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., treating circulatory disorders).

One skilled in the art would have been motivated to prepare compounds embraced by the teachings of Reitz et al. to arrive at the instant claimed compounds with the expectation of obtaining additional beneficial N-substituted imidazol-2-one compounds which would be useful in treating circulatory disorders, glaucoma, etc. The instant claimed N-substituted imidazol-2-one compounds would have been suggested to one skilled in the art and therefore, the instant claimed compounds would have been obvious to one skilled in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to

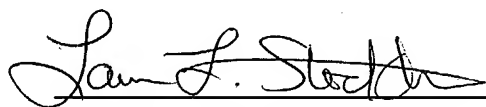
Application/Control Number: 10/649,210
Art Unit: 1626

Page 9

2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

The Official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

A handwritten signature in cursive script, reading "Laura L. Stockton", written over a horizontal line.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

March 16, 2004